TAB 338

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

THE ROXANE DEFENDANTS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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Another mailing announced the launch of "NOVAPLUS™ Ipratropium Bromide." (Tab 155, NovaPlus Ipratropium Bromide Agreement Launch Package at RLI-AWP 00122465-70.)

149. From June 1999 until May 2004, the NovaPlus label ipratropium bromide was sold exclusively to Novation members under the private-label agreement. (Tab 155, NovaPlus Ipratropium Bromide Agreement Launch Package at RLI-AWP 00122465-70; Tab 162, BOEH01522558, "The Multi-Source Gold Sheet, March 22, 2004" (March Gold Sheet); Tab 163, BOEH02953413, "The Multi-Source Gold Sheet, April 8, 2004" (April Gold Sheet); Tab 164, BOEH02953409, "The Multi-Source Gold Sheet, May 3, 2004" (May Gold Sheet).)

150. Roxane and Novation's Agreement was initially set to expire in January 2004. (Tab 155, NovaPlus Ipratropium Bromide Agreement Launch Package, RLI-AWP 00122465-70). But due to lack of demand, the decision to discontinue NovaPlus ipratropium bromide was made in June 2003 and official notice was sent to Novation in July 2003. (Tab 165, BOEH04310697, 7-11-03 Ltr. from L. Paoletti to R. Day). The NovaPlus-label ipratropium bromide product was discontinued between March-May 2004. (Tab 162, March Gold Sheet at BOEH01522558; Tab 163, April Gold Sheet at BOEH02953413; Tab 164, May Gold Sheet at BOEH02953409.)

B. The Medicare Regulatory Framework For Hospital Reimbursements Under The Medicare Parts A and B.

151. Drugs dispensed to Medicare beneficiaries during inpatient hospital stays are not paid for separately but are reimbursed along with procedures as part of a bundled package through diagnosis-related groups under Medicare Part A. *See* 42 U.S.C. § 1395ww(a)(4).

152. Beginning on July 1, 2000, drugs dispensed to Medicare beneficiaries during outpatient hospital visits to Hospital Outpatient Departments (OPDs), including hospital pharmacies, are reimbursed under Medicare Part B's Outpatient Prospective Payment System

(OPPS). *See* 42 U.S.C. § 1395l(t)(2); 65 Fed. Reg. 18434, 18436 (April 7, 2000) Similar to Medicare Part A, Medicare Part B's OPPS typically reimburses drugs dispensed in OPDs on a "package" basis under an Ambulatory Payment Classification System, which is comprised of all items and services for that procedure, identified by their individual J-codes and/or other HCPCS codes—meaning that under the OPPS, Medicare Part B pays for all items and services related to a procedure with a lump sum—not for individual drugs based on claims made under J-codes. *See* 42 U.S.C. § 1395l(t)(2); 42 C.F.R. §§ 419.21, 419.31; addenda to 65 Fed. Reg. 18434 (April 7, 2000).

153. Because Novation's membership consists almost exclusively of hospitals, and given the structure of the Medicare regulatory scheme, it is unlikely that very many NovaPlus ipratropium bromide prescriptions were reimbursed under the Medicare program. (Tab 45, 5-18-09 Scott Morton Dep. 341-44, 346-48.)

154. According to plaintiffs' expert, Dr. Mark G. Duggan, "Roxane's NovaPlus products, at least for Medicaid, account for a miniscule share of all Medicaid prescriptions for ipratropium bromide." (Tab 18, 3-5-09 Duggan Dep. 187.) Dr. Duggan uncovered only 48 NovaPlus ipratropium bromide prescriptions paid for by the Medicaid program throughout the entire United States during the six-year period that NovaPlus ipratropium bromide was sold. (*Id.* 186-188; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 127.)

155. Dr. Duggan estimated, based on an extrapolation from the number of Medicaid prescriptions that perhaps only 150 NovaPlus ipratropium bromide prescriptions were reimbursed out of the 12.8 million ipratropium bromide prescriptions paid for under Medicare Part B over the same span. (Tab 18, 3-5-09 Duggan Dep. 188; Tab 20, 5-18-09 Duggan Dep. 156-57; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 127.)

C. The DMERCs' Inconsistent And Private Procedures For Constructing Pricing Arrays And Establishing Payment Rates.

156. HCFA and later CMS delegated the task of setting the maximum reimbursement rate for Medicare Part B drugs dispensed via durable medical equipment (DME) to private contractors called durable medical equipment regional carriers (DMERCs). *See* 42 U.S.C. § 1395m(a)(12); 42 C.F.R. § 421.210. The country is divided into four DME regions and each DMERC, following HCFA/CMS guidelines, sets the maximum Medicare rate for DME drugs within its region. *See* 42 U.S.C. § 1395m(a)(12); 42 C.F.R. § 421.210; http://www.ezdme.com/aboutez/dmerc_regions.htm.

157. During the pertinent time period there were four DMERCs that processed ipratropium bromide claims under Medicare Part B. (Tab 50, 2-29-08 Stone Dep. 422-23.) The four DMERCs were generally known as DMERC-A, AdminaStar Federal, Palmetto, and Cigna. (Tab 18, 3-5-09 Duggan Dep. 130-31.)

158. Throughout the relevant period, in order to maintain oversight and facilitate compliance with the applicable regulations, HCFA and CMS would issue program memoranda to the carriers, including the DMERCs, which were "instruction[s] to our carriers who administer the Medicare program." (Tab 40, Niemann Dep. 365; *see also* Tab 51, 4-25-07 Tawes Dep. 435 ("A program memorandum is a memo sent to intermediaries or carriers by CMS headquarters").)

159. By regulation, when pricing drugs for reimbursement purposes under Medicare Part B, the DMERCs were required to utilize the lesser of the "median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological." 42 C.F.R. § 405.517 (emphasis added); *see also* Tabs 167-168, Roxane Exs. 41 and 42, AWQ025-0722 and AWQ025-0880 (Medicare Professional Reimbursement Desk Procedure - Drug Pricing Procedure).

160. Each of the DMERCs independently set maximum reimbursement rates for its region by consulting the pricing compendia, converting the published AWPs of the drugs selected from the compendia into unitized prices by dividing the published AWPs by the quantity or strength of the packaged drug, compiling those prices into worksheets called pricing arrays, and then calculating the median price of these arrays. (Tab 22, 8-26-08 Eiler Dep. 47-49, 116; Tab 30, Helton Dep. 22-23; Tab 167, Roxane Ex. 41 at AWQ025-0722– AWQ025-0725 (Drug Pricing Procedure); Tab 169, Roxane Ex. 100 at AWP034-0462–AWP034-0466 (Drug Pricing Procedure); Tab 170, Abbott Ex. 524 at HHD008-0282– HHD008-0287 (Medicare Professional Reimbursement Desk Procedure).)

161. When the median AWP of the generic sources of a drug and the lowest AWP for a brand source were equivalent, the DMERCs used one of the prices as the maximum allowable rate, but could not tell which price actually set the reimbursement rate. (Tab 30, Helton Dep. 230-31; Tab 49, 2-28-08 Stone Dep. 194.)

162. The DMERCs' arrays and classification of drugs were not publicly available. (Tab 22, 8-26-08 Eiler Dep. 157-58.)

163. Although HCFA directives to the DMERCs allowed for consideration of a wide variety of published sources, such Red Book, Blue Book, or Medispan, in practice the DMERCs limited their review exclusively to the Red Book compendium. (*See, e.g.*, Tab 171, Abbott 1015, HHC021-0030, December 1998 HCFA Transmittal; Tab 22, 8-26-08 Eiler Dep. 27-28, 47-48, 116-19, Tab24, 9-23-08 Eiler Dep. 481-82; Tab 30, Helton Dep. 22-23, 36, 37; Tab 49, 2-28-08 Stone Dep. 34-35, 65-66, 87-88; Tab 183, Decl. of C. King ¶ 7; Tab 172, Roxane Ex. 51 at AWQ029-00326–AWQ029-00328 (Uniform Drug Pricing Project).)

164. During the relevant period, the four DMERCs updated their pricing arrays at different times, and also selected prices from different Red Book sources that were not always consistent. (Tab 22, 8-26-08 Eiler Dep. 125-26, 135-36; Tab 30, Helton Dep. 108, 224-26, 237; Tab 50, 2-29-08 Stone Dep. 284-86.) For example, sometimes one DMERC would receive a monthly update earlier than the other DMERCs, so they would use the update while the other DMERCs would use an outdated version. (Tab 22, 8-26-08 Eiler Dep. 135-36; Tab 30, Helton Dep. 158-59.)

165. The inconsistent use of different versions of Red Book sometimes resulted in drugs being omitted from a DMERC's array in one quarter and then reappearing in a later quarter. (Tab 23, 8-27-08 Eiler Dep. 280-86, 295-96.)

166. The DMERCs varied widely in the sources of Red Book that they relied upon, with some DMERCs using the annual update, others consulting the monthly updates or quarterly electronic CDs, and others using both at times. (Tab 22, 8-26-08 Eiler Dep. 47-48, 125-26, 133-34; Tab 24, 9-23-08 Eiler Dep. 481-82; Tab 30, Helton Dep. 44-45, 224-26; Tab 49, 2-29-08 Stone Dep. 113; Tab 50, 2-29-08 Stone Dep. 284-85; Tab 183, Decl. of C. King ¶¶ 7, 9; Tab 168, Roxane Ex. 42 at AWQ025-0876–AWQ025-0887 (12-1-99 Ltr. from R. Stone to C. Carpenter).)

167. Each DMERC separately decided how to construct the arrays by reviewing the descriptions in the compendia, and by also consulting other external resources such as reference guides and medical directors that each DMERC had on staff and by exercising their judgment. (Tab 22, 8-26-08 Eiler Dep. 27, 48-49, 58-59, 119-20, 149, Tab 24, 9-23-08 Eiler Dep. 487-88; Tab 30, Helton Dep. 89, 160-61; Tab 49, 2-28-08 Stone Dep. 77-78, 86, Tab 50, 2-29-08 Stone

reduce inconsistencies—usually without any participation by HCFA/CMS. (Tab 22, 8-26-08 Eiler Dep. 127-28, 135-36, 153-54, 166-67, 171-72; Tab 30, Helton Dep. 99-100, 144-46, 169-71, 277-78; Tab 50, 2-29-08 Stone Dep. 282-83; Tab 183, Decl. of C. King ¶ 17; Tab 168, Roxane Ex. 42 at AWQ025-0876–AWQ025-0887 (12-1-99 Ltr. from R. Stone to C. Carpenter); Tab 172, Roxane Ex. 51 at AWQ029-00326–AWQ029-00328 (Uniform Drug Pricing Project); Tab 173, Roxane Ex. 52 at AWQ029-000104– AWQ029-000105 (5-15-01 E-mail from R. Stone to C. King, C. Eiler, C. Helton, B. Douglas, and V. Brantley); Tab 169, Roxane Ex. 100 at AWP034-0462–AWP034-0466 (Drug Pricing Procedure); Tab 174, Roxane Ex. 102 at AWP039-1420 (7-6-99 E-mail from C. King to C. Eiler).) The DMERCs did not, however, coordinate their construction of arrays or ensure that all four DMERCs were using the same published prices or classifying drugs in an identical way. (Tab 22, 8-26-08 Eiler Dep. 153-54; Tab 30, Helton Dep. 108-09, 144-46; Tab 172, Roxane Ex. 51 at AWQ029-00326–AWQ029-00328 (Uniform Drug Pricing Project; Tab 174, Roxane Ex. 102 at AWP039-1420 (7-6-99 E-mail from C. King to C. Eiler).)

D. HCFA's Regulations And Directives Distinguished Generics From Brands Based On Whether The Drug Used Its Generic Chemical Name.

174. On November 2, 1998, HCFA implemented a final rule that revised its payment methodology for generics under Medicare Part B to include consideration of AWPs for brand drugs. *See* 63 Fed. Reg. 58813, 58849 (1998) (Tab 112, Abbott Ex. 209). HCFA adopted a payment formula for generic drugs that required Medicare carriers, including the DMERCs, to compare "the lower of the median price of the generic AWPs" with "the lowest brand name AWP," and then pay the lower amount. *Id.*; *see also* 42 CFR § 405.517 (1998).

AWQ058-0950, ("Medicare Supplier Bulletin Region B DMERC"); Tab 177, Dey Ex. 126 at HHD011-0224, ("Cigna DMERC: Nebulizer Medications".)

178. In December 1998, HCFA issued a Program Memorandum that directed the Medicare DMERCs to implement the November 1998 regulatory changes. (Tab 171, Abbott Ex. 1015 at HHC201-0030 (HCFA Program Memorandum, Transmittal No. AB-98-76); Tab 175, Abbott Ex. 529 at AWQ025-1349 (HCFA Program Memorandum, Transmittal No. AB-98-76).) HCFA directed the carriers to obtain published AWPs from "sources such as the Red Book, Blue Book, or Medispan." (*Id.*)

E. The DMERCs' Idiosyncratic And Private Classification Criteria Ignored And Were Inconsistent With HCFA's Regulatory Definitions And Directives.

179. Throughout the relevant period the DMERCs constructed separate arrays for generic and brand versions of ipratropium bromide to determine whether the median of the generic AWPs was lower than the lowest brand AWP. (Tab 24, 9-23-08 Eiler Dep. 547; Tab 18, 3-5-09 Duggan Dep. 146)

180. In determining whether a drug was a generic versus a brand, the DMERCs' Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure ("Drug Pricing Procedure") did not use the regulatory definition that a "brand" product is defined as a product that is marketed under a labeled name that is other than the generic chemical name of the drug or biological." (Tab 22, 8-26-08 Eiler Dep. 145-46, Tab 24, 9-23-08 Eiler Dep. 485, 547-49 ("Q: Now I want to suggest to you, Ms. Eiler that Novaplus actually has always been a generic product, not a brand product. And that if one – I want you to assume that if one had done additional research, the generic status of that drug might have been discovered . . ."), 558-603 ("Q: Okay. I'd like you to assume today that in fact they're [Novaplus NDCs] generic drugs, and that if you have done some additional research, besides just looking at the RedBook, you

might have determined that they were in fact generics."); Tab 30, Helton Dep. 253-54; Tab 168, Roxane Ex. 42 (12-1-99 Ltr from R Stone to C. Carpenter), Tab 169, Roxane 100 (Drug pricing Procedure).) Instead, the Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure directed the DMERCs to use the following methodology to determine whether a drug was a brand drug:

> To determine if a drug is generic or brand, look at the bold face upper case name of the drug [in the Drug Topics Red Book publication]. If there is another name for the drug immediately below it in lower case letters (the generic name), the entries following are generally brands. If there is no lower case drug name immediately below the bold face upper case name, the bold face upper case name is the generic name and all the entries below are generics. In either case, if an entry below the drug name refers to another page, that entry would be for a brand name. If there is a question as to whether a drug is brand or generic, consult the PDR Generics, telephone the drug company or **Red Book** (1-800-222-3045).

(Tab 168, Roxane Ex. 42 at AWQ025-0881-82, (12-1-99 Letter from R. Stone to C. Carpenter – Drug Pricing Procedure) (emphasis in original); (*see also* Tab 22, 8-26-08 Eiler Dep. 145-46; Tab 24, 9-23-08 Eiler Dep. 485, 547-49; Tab 169, Roxane 100 (Drug Pricing Procedure).

181. The DMERCs sometimes determined whether a drug was a brand by whether it had the word "See" in the Red Book, indicating a cross reference. (Tab 30, Helton Dep. 253-54)

182. The DMERCs also sometimes made the brand/generic classification without consulting the printed Red Book. (Tab 24, 9-23-08 Eiler Dep. 600-03.) On those occasions, DMERCs would review certain files on a Red Book CD database that did not have the same capitalization convention as the printed volumes but instead listed the brand drugs in separate data files. (*Id.*; Tab 50, 2-29-08 Stone Dep. 305-310.)

183. Once a DMERC made the initial determination of whether a drug was a generic or a brand, the DMERC would carry that same classification through in subsequent quarters unless "some notation in the RedBook . . . indicated it had changed from branded to generic or vice versa." (Tab 24, 9-23-08 Eiler Dep. 603.)

184. The Annual Red Book did not begin listing the NDCs for the NovaPlus label ipratropium bromide inhalation solution until 2001. (*Compare* Tab 154, 2001 RedBook at 368 *with* Tab 178, 2000 Red Book at 369.)

185. In the 2001 Annual Red Book, under the bold-faced, upper-case **IPRATROPIUM BROMIDE** heading in the left-hand column, the Red Book listed all ipratropium products by manufacturer. (Tab 154, 2001 Red Book at 368.) For example, under the **IPRATROPIUM BROMIDE** heading it listed generic ipratropium bromide products by **(Alpharma USPD), (Dey), (Roxane)** and **(Zenith Goldline)**. (*Id.*)

186. The 2001 Annual Red Book listed the three NovaPlus label ipratropium bromide NDCs (0054-8404-11, 0054-8404-13, 0054-8404-21) directly underneath to the Roxane label ipratropium bromide NDCs (0054-8402-11, 0054-8402-13, 0054-8402-21). (*Id.*) All six NDCs were listed under the "**(Roxane)"** manufacturer designation. (*Id.*)

187. The 2001 Annual Redbook listed identical AWPs for the three Roxane label NDCs and the corresponding NovaPlus label NDCs of the same package sizes. (*Id.*) For example, the Roxane-label 2500 ml 25s unit dose vial (NDC 00054-8402-11) listed an AWP of 44.06; the NovaPlus-label 2500 ml 25s unit dose vial (NDC 00054-8404-11) listed the same AWP of 44.06. (*Id.*)

188. The 2001 Annual Red Book descriptions for the three NovaPlus label NDCs were identical to the corresponding package sizes for the three Roxane label NDCs. For example, all six NDCs contained the description "SOL, IH (S.D.V. […] PROTECTAPAK 0.02%." (*Id.*)

189. The 2001 Annual Red Book listings for the NovaPlus-label NDCs did not contain the word "NovaPlus" anywhere under any of the **IPRATROPIUM BROMIDE** listings or **(Roxane)** NDC sub-listings. (*Id.*)

190. The 2001 Annual Red Book listings for the NovaPlus label NDCs did not contain the word "See" next to the NovaPlus label or Roxane label NDCs. (*Id.*)

191. The 2001 Annual Red Book contained a listing under the **IPRATROPIUM BROMIDE** heading that read as follows: **(Boehr Ingelheim)** *See ATROVENT.* (*Id.*)

192. The 2001 Annual Red Book listing for the Roxane label or NovaPlus label ipratropium bromide did not contain the word "ipratropium bromide" in either bold face or capitals under the **(Roxane)** listing. (*Id.*)

193. The 2001 Annual Red Book listing did not contain a separate entry for "IPRATROPIUM BROMIDE NOVAPLUS." (*Id.*)

194. Other than different NDC numbers, the NovaPlus label NDC listings in the 2001 Annual Red Book were identical to the corresponding package sizes of the Roxane-label NDCs. (*Id.*)

195. The 2001 Annual Red Book listings for the NovaPlus NDCs identified them as generic drugs under the Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, 12-1-99 Ltr. from R. Stone to C. Carpenter, Drug Pricing Procedure). There was a "bold face upper case name," (*i.e.*, **IPRATROPIUM BROMIDE**) in the 2001 Annual Red Book listing, but there was not "another name for the drug immediately below it in lower case name letters (the generic name)," and thus the entry did not indicate a brand. (Tab 154, 2001 Red Book at 368; *supra* ¶¶ 46, 51-60.) Because "there is no lower case drug name immediately below" **IPRATROPIUM BROMIDE,** ipratropium bromide "is the generic name and all the entries below are generics." (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, 12-1-99 Ltr from R Stone to C Carpenter.)

196. The 2001 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the Adminastar DMERC for distinguishing brand from generic drugs. (Tab 24, 9-23-00 Eiler Dep. 547-49).

197. The 2001 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the Cigna DMERC for distinguishing brand from generic drugs. (Tab 30, Helton Dep. 253-54). Specifically, the word "see" was not next to any of the NovaPlus-NDCs. (Tab 154, 2001 Red Book at 368). According to the Cigna DMERC's criteria for identifying brand drugs, the 2001 Annual Red Book listing for "ATROVENT" identified that product as a brand product for ipratropium bromide because it had the word "See" and a cross-reference next to it. (Tab 30, Helton Dep. 253-54).

198. In the 2002 Annual Red Book, under the bold-faced, upper-case **IPRATROPIUM BROMIDE** heading in the left-hand column, the Red Book listed all ipratropium products by manufacturer. (Tab 180, 2002 Red Book at 389) For example, under the **IPRATROPIUM BROMIDE** heading it listed generic ipratropium bromide products by **(Alpharma USPD), (Dey), (Roxane)** and **(Zenith Goldline)**. (*Id.*)

199. The 2002 Annual Red Book listed the three NovaPlus-label ipratropium bromide NDCs (0054-8404-11, 0054-8404-13, 0054-8404-21) directly underneath to the Roxane label ipratropium bromide NDCs (0054-8402-11, 0054-8402-13, 0054-8402-21). (*Id.*) All six NDCs were listed under the "**(Roxane)"** manufacturer designation. (*Id.*)

200. The 2002 Annual Red Book listed identical AWPs for the three Roxane-label NDCs and the corresponding NovaPlus-label NDCs of the same package sizes. (*Id.*) For example, the Roxane-label 2500 ml 25s unit dose vial (NDC 00054-8402-11) listed an AWP of

44.06; the NovaPlus-label 2500 ml 25s unit dose vial (NDC 00054-8404-11) listed the same AWP of 44.06. (*Id.*)

201. The 2002 Annual Red Book descriptions for the three NovaPlus label NDCs were identical to the corresponding package sizes for the three Roxane-label NDCs. For example, all six NDCs contained the description "SOL, IH (S.D.V. […] PROTECTAPAK 0.02%." (*Id.*)

202. The 2002 Annual Red Book listings for the NovaPlus label NDCs did not contain the word "NovaPlus" anywhere under any of the **IPRATROPIUM BROMIDE** listings or **(Roxane)** NDC sub-listings. (*Id.*)

203. The 2002 Annual Red Book listings for the NovaPlus label NDCs did not contain the word "See" next to the NovaPlus label or Roxane label NDCs. (*Id.*)

204. The 2002 Annual Red Book contained two listings under the **IPRATROPIUM BROMIDE** heading that read as follows: **(Boehr Ingelheim Pharm)** *See ATROVENT.* (*Id.*)

205. The 2002 Annual Red Book listing for the Roxane label or NovaPlus label ipratropium bromide did not contain the word "ipratropium bromide" in either bold face or capitals under the **(Roxane)** listing. (*Id.*)

206. The 2002 Annual Red Book listing did not contain a separate entry for "IPRATROPIUM BROMIDE NOVAPLUS." (*Id.*)

207. Other than different NDC numbers, the NovaPlus label NDC listings in the 2002 Annual Red Book were identical to the corresponding package sizes of the Roxane-label NDCs. (*Id.*)

208. The 2002 Annual Red Book listings for the NovaPlus NDCs identified them as generic drugs under the Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, (Medicare Professional

Reimbursement Desk Procedure, Drug Pricing Procedure)). There was a "bold face upper case name," (*i.e.*, **IPRATROPIUM BROMIDE**) in the 2002 Annual Red Book listing, but there was not "another name for the drug immediately below it in lower case name letters (the generic name)," and thus the entry did not indicate a brand. (Tab 180, 2002 Red Book at 389; *supra* ¶¶ 46, 64-73.) Because "there is no lower case drug name immediately below" **IPRATROPIUM BROMIDE,** ipratropium bromide "is the generic name and all the entries below are generics." (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, 12-1-99 Ltr. from R. Stone to C. Carpenter - Drug Pricing Procedure AWQ025-0876-79)).

209. The 2002 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the Adminastar DMERC for distinguishing brand from generic drugs. (Tab 24, 9-23-08 Eiler Dep. 547-49).

210. The 2002 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the Cigna DMERC for distinguishing brand from generic drugs. (Tab 30, Helton Dep. 253-54). Specifically, the word "see" was not next to any of the NovaPlus-NDCs. (Tab 180, 2002 Red Book at 389). According to the Cigna DMERC's criteria for identifying brand drugs, the 2002 Annual Red Book listing for "ATROVENT" identified that product as a brand product for ipratropium bromide because it had the word "See" next to it. (Tab 30, Helton Dep. 253-54).

211. Each time the DMERCs utilized the quarterly Red Book electronic CD databases by uploading a new electronic CD, the data provided on the previous electronic CD was deleted. (Tab 23, 8-27-08 Eiler Dep. 295.) The DMERCs could not keep a record of the data from the previous electronic CD other than by printing a hard copy. (*Id.*)

212. The few hard copy printouts produced by the DMERCS list *all* drugs—brand and generic—in all-capital letters. (Tab 24, 09-23-08 Eiler Dep. 600-03; Tab 179, AWP039-3207 (July 2000 Red Book for Windows printout); Tab 180, AWP038-0705 (April 2002 Red Book for Windows printout); Tab 178, AWP039-2444 (April 2000 Red Book for Windows printout).)

213. Although the internal procedures required the DMERCs to consult manufacturers, the Physicians Desk Reference book, or the Red Book itself if questions arose about the classification of a drug, there is no evidence that any DMERC did so with respect to classifying iptratropium bromide products. (Tab 22, 8-26-08 Eiler Dep. 119-20.)

214. The DMERCs did no additional research besides looking at RedBook to determine whether a drug was a generic or a brand. (Tab 24, 9-23-08 Eiler Dep. 559.) The DMERCs did not verify their classifications using First DataBank, Medispan, or any other compendia besides RedBook. (*Id.*)

215. First DataBank is a widely-used pricing compendium relied on by commercial and government third-party payors, including many State Medicaid programs, as well as others in the pharmaceutical industry to determine the generic status of NDCs. (Tab 182, Aff. of F. Scott Morton ¶ 7.)

216. In order to assist these entities in determining whether a drug is a generic or brand, First DataBank publishes a database containing several different "classification indicators." (Tab 182, Aff. of F. Scott Morton ¶ 3.)

217. Among others, these indicators include the "generic name drug indicator" and the "generic price indicator." (Tab 182, Aff. of F. Scott Morton ¶ 3.)

218. During the relevant time period, all of First DataBank's classification indicators were ***identical*** for Roxane-label and NovaPlus label ipratropium bromide. (Tab 182, Aff. of F. Scott Morton ¶ 6.)

219. For example, under "generic name indicator," First DataBank listed ***both*** the Roxane-label and NovaPlus-label ipratropium bromide as "Generically named AND multiple source." (Tab 182, Aff. of F. Scott Morton ¶¶ 5-6.)

220. Similarly, under "generic price indicator," First DataBank listed ***both*** the Roxane-label and NovaPlus-label ipratropium bromide as "Priced as a lower cost alternative." (Tab 182, Aff. of F. Scott Morton ¶¶ 5-6.)

F. Some Of The DMERCs Inconsistently Classified The Roxane And NovaPlus-Label Ipratropium Bromide Products As *Both* Brands And Generics, At Differing Times.

221. The four DMERCs varied considerably in their classifications of the NovaPlus and Roxane label ipratropium bromide products. (Tab 18, 3-5-09 Duggan Dep. 146). Of the four DMERCs, only DMERC-A consistently placed the NovaPlus and Roxane labeled products in its generic arrays throughout the pertinent time period. (Tab 183, Ex. A to Decl. of C. King at AWQ071-0043, AWQ071-0047, AWQ071-0052, AWQ071-0059, AWQ071-0063, AWQ071-0066, AWQ071-0070, AWQ071-0073, AWQ071-0077 (DMERC-A arrays).) The remaining three DMERCs classified either the NovaPlus label product or the Roxane label as a brand, and, in some instances, alternated the classification of the *same* product across time periods. (*See, e.g.*, Tab 24, 9-23-08 Eiler Dep. 549, 552-554; Tab 184, Eiler U.S. Ex. 11 (AdminaStar Federal Arrays) at AWP038-0704-05; Tab 185, Roxane 118 at AWP033-1352.)

222. The Palmetto DMERC placed the NovaPlus product in its generic arrays from April to July 2003, even though it had previously classified the product as a brand in prior arrays. (Tab 186, Roxane Ex. 46 at AWQ022-0074-AWQ-022-077.) Beginning in July 2003, Palmetto